APR 2 5 2013

510 (K) Summary

Ref: K123282

Mixed Bed Deionization (DI) and Carbon Exchange Tanks

Revision Date: February 25, 2013

1. **Prepared/Submitted by:** Ultrapure & Industrial Services, LLC (UIS)
   4429 Mint Way, Dallas, TX 75236

   Contact Person: Wasif Asghar
   General Manager
   Telephone: (972) 432.9951

2. **Devise Name:** Deionization and Carbon Exchange Tanks for Dialysis

3. **Devise Classifications:** Water Purification Component
   Class II Medical Device
   21 CFR 876.5665, Product Code – FIP

4. **Predicate Devise:** AmeriWater Dialysis and Carbon Exchange Tanks (K991519)

UIS Model Numbers:

Deionization Tank Model No.	Carbon Tank Model No.
UIS-618-MB-D	UIS-618-GAC
UIS-818-MB-D	UIS-818-GAC
UIS-844-MB-D	UIS-844-GAC
UIS-1047-MB-D	UIS-1047-GAC
UIS-1447-MB-D	UIS-1447-GAC

5. Device Description:

Deionizers: Ultrapure & Industrial Services **Mixed Bed Deionization** Exchange Tanks (DI) are Fiberglass Reinforced Polypropylene (FRP) tanks filled with mixed bed deionization resin. The tank sizes are common for the Dialysis industry with similar inlet and outlet fittings, PVC or Noryl heads and tank distributors. The DI Exchange Tanks are dedicated for ion exchange resin only. Our tanks are designed to deliver Association for the Advancement of Medical Instrumentation (AAMI) standard water through an ion exchange process **to remove contaminantes from water being fed to the system. The DI system exchanges hydrogen ion (H+) for cations and hydroxyl ions (OH-) for anions in the feed water. The hydrogen and hydroxyl ions then combine to form pure water (H2O).** The tanks are based on the AmeriWater Dialysis Deionizer Exchange Tanks K991519.

Similar to predícate AmeriWater, Ultra-Pure segregated aseptic exchange deionizer service in an on-line worker/polisher arrangement with a temperature compensated 1 megohm/cm resistance light monitor with audible alarm between the worker/polisher and a 0-19 megohm/cm temperatura compensated digital readout resistance meter with adjustable remote audio and visual alarm. Upon exhaustion, these tanks are replaced with other Deionization Tanks containing newly regenerated resin or with new resin altogether.

Divert to drain is now required by AAMI. When deionizer water resistivity drops below 1 megohm the deionized water dumps to drain.

UIS Deionizer Exchange Tank Models

Model Number	Cubic Feet	Flow in GPM
UIS-618-D	0.27	0.5
UIS-818-D	0.47	1.0
UIS-844-D	1.25	2.5
UIS-1047-D	1.90	3.8
UIS-1447-D	3.60	7.2

Carbon: Ultrapure & Industrial Services **Carbon Exchange** Tanks are Fiberglass Reinforced Polypropylene (FRP) tanks filled with new activated carbon. **This carbón filtration, often referred to as granular activated carbón (GAC), will remove chlorine and chloramine that are almost always present in the source water through a chemical process knows as "adsorption".** The tank sizes are common for the Dialysis industry with similar inlet and outlet fittings; PVC or Noryl heads and tank distributors. The Carbon Exchange Tanks are dedicated for carbon only. **Ultrapure & Industrial Services always recommends that two tanks be installed in series, with the first tank providing the primary purification and the second tank serving as backup. Same recommendation is offered by the predicate.** The tanks are based on the AmeriWater Dialysis Carbon Exchange Tanks K991519.

Dialysis segregated exchange process carbon service utilizes new virgin coal based granular activated carbon (GAC) of 12X40 mesh size with an iodine number of 1000 or greater.
The tanks are disinfected with chlorine and cleaned before delivery to the dialysis application. Batch codes and dates are used to insure quality and freshness of the tanks. The tanks are re-bedded under our FDA/QS system with batch control of capacity, quality and microbiological control. Ultrapure & Industrial Services process includes a use of medical-grade carbon only followed by a 24-hour soak to fully wet the carbon followed by complete back-washing to remove any contaminants and provide a more natural pH product.

UIS Carbon Exchange Tank Models		
Model Number	**Cubic Feet**	**Flow in GPM**
UIS-618-GAC	0.27	0.5
UIS-818-GAC	0.47	1.0
UIS-844-GAC	1.25	2.5
UIS-1047-GAC	1.90	3.8
UIS-1447-GAC	3.60	7.2

6. **Indication of Use:**

A. **The Ultrapure & Industrial Services (UIS) Deionization Tanks are exchangeable/rechargeable mix bed tanks intended to remove ions from the water to a sufficient level to allow safe treatment of Hemodialysis patients. These deionization tanks are not to be used alone, but are intended to be a part of a larger water treatment system employing adequate pre-treatment and post treatment. Upon, exhaustion, these tanks will be replaced with other tanks containing newly regenerated resin, or new resin altogether.**

Deionizer Tank Models	
Model Number	**Cubic Feet**
UIS-618-MB-D	0.27
UIS-818-MB-D	0.48
UIS-844-MB-D	1.25
UIS-1047-MB-D	1.90
UIS-MB-1447-D	3.60

B. **The Ultrapure & Industrial Services Carbon Exchange Tanks are activated carbon tanks intended to remove chlorine and chloramines from the water to allow safe treatment of Hemodialysis patients. These carbon tanks are not be used alone, but are intended to be part of a larger water treatment system employing adequate pre-treatment and post-treatment. Upon exhaustion, these tanks will be replaced with other tanks containing new activated carbon.**

Carbon Tank Models	
Model Number	**Cubic Feet**
UIS-618-GAC	0.27
UIS-818-GAC	0.47
UIS-844-GAC	1.25
UIS-1047-GAC	1.90
UIS-1447-GAC	3.60

All Ultrapure & Industrial Services Deionizer and Carbon Exchange Tank Service for hemodialysis are intended to be used in a hemodialysis facility according to ANSI/AAMI-RD62:2006 standards to supply purified water for use in hemodialysis.

7. **Comparison to Predicate:** AmeriWater Exchange Tanks (K991519)

Ultrapure & Industrial Services, LLC exchange tanks for dialysis are substantially equivalent to the currently marketed AmeriWater Dialysis tanks and have not altered the fundamental scientific technologies used in the predicate device.
The intended use of the exchange tanks for dialysis is the same as the intended use of the AmeriWater predicate device (K991519).

Substantial Equivalence

(Predicate Device) Ameriwater Dialysis Deionizer Exchange Service (K991519)	**Ultrapure & Industrial Services, LLC Dialysis Deionizer Exchange Service**
Carbon Filtration. Calgon's Centaur	*Carbon Filtration. Medical Grade Resin Tech (AGC-40 MG) carbon.
FRP tanks manufactured by Park International (Now Pentair), brand "Park"	**FRP tanks manufactured by Pentair under brand name Park / Structure
MBD-10 Resin manufactured by ResinTech	MBD-10 Resin manufactured by ResinTech
Resi-Lite 1 megohm audio/visual alarm positioned between worker and polisher	Resi-Lite 1 megohm audio/visual alarm positioned between worker and polisher
Interconnecting Tubing. High Purity PVC.	Interconnecting Tubing. High Purity PVC.
Connectors; Made of glass filled Noryl	Connectors; Made of glass filled Noryl
Heads and fill plugs: PVC schedule 80 machined head with PVC PVC schedule 80 fill plug.	***Heads and fill plugs: PVC schedule 80 machined head with PVC schedule 80 fill plug or Glass filled Noryl head and fill plug.
PVC schedule stand pipe and distributor basket	PVC schedule stand pipe and distributor basket

MINOR DIFFERENCE

* *For carbon media, the predicate uses Calgon's Centaur while Ultrapure & Industrial Services device uses ResinTech Medical Grade Activated Carbon AGC-40 MG. It is much superior premium grade carbon especially prepared for use in medical industry and is fully tested to AAMI standards. Both medias meet AAMI/RD62:2006 standards.*

** *Park International is now owned by Pentair Water Treatment. Tanks are sold under the name of Park and Structure. Predicate AmeriWater uses the same manufacturer.*

****Heads and Fill plugs: Ultrapure and Industrial Services, LLC uses both PVC schedule 80 machined head with PVC schedule 80 fill plug (predicate AmeriWater K991519) and glass filled Noryl head and fill plug (predicates Aqua Systems K092481).*

Note: All components used meet or exceed ANSI/AAMI RD62-2006 standards.

Ultrapure and Industrial Services exchange tanks for both Deionization (DI) and Carbon (GAC) are fiberglass reinforced polypropylene (FRP) tanks. These tanks are 100% non-corrosive with inner-shell material of Seamless Polyethylene. The design parameters meet and exceed NSF, ASME & ANSI/AAMI RD62-2006 standards. Tanks are dedicated either for deionization or carbon and are not interchangeable. The tanks and sizes are similar to those used by the predicate AmeriWater (K991519) [Also predicates Aqua Sciences K102892]. Sizes are common and widely used in the dialysis industry and tank size utilization is based on water volume required for each individual clinic. Ultrapure & Industrial Services purchase all tanks from the same manufacturer as the predicate AmeriWater.
Deionization tanks from both Ultrapure & Industrial Services and AmeriWater are utilized to remove dissolved solids from the water. Both companies utilize mixed bed resin, consisting of cations and anions resins to remove the charged particles in the water. Both utilize parts and materials that are NSF and/or FDA approved.

Activated carbon tanks/filtration is utilized by both Ultrapure & Industrial Services and AmeriWater to filter out chlorine and chloramines from the water. Ultrapure utilizes the "highest quality Medical Grade activated carbon that meets NSF and AAMI standards.

Both companies use two (2) carbon tanks in a series configuration. Both Ultrapure & Industrial Services and AmeriWater recommend that chlorine and chloramines are checked before each patient shift. Both companies utilize activated carbon with an iodine number of 1000 or greater. Ultrapure & Industrial Services recommends using dual carbon filtration in series in every dialysis water system installed, including single patient systems.

8. Performance Testing

A system performance test was run by simulating operational conditions. A system consisting of Carbon, and DI resins was set in place and operated. Quality testing of chlorine, chloramines and resistivity levels were monitored to ensure performance.

To qualify performance six (06) water samples were taken for validation purposes. Three samples of the raw feed water were drawn for use as a beginning foundation of the need for treatment. Three samples were taken from the final DI unit to validate performance meeting AAMI RD62 standards.

The water samples were sent to three separate labs. To test for AAMI standards, a raw water feed sample and a treated water feed sample was sent to AmeriWater and Culligan Laboratories. To test for TOC, a raw water feed sample and a treated water feed sample was sent to Oxidor Testing Laboratory.

Analysis results from AmeriWater and Culligan show AAMI standard performance. Results from Oxidor Testing Laboratories show a reduction of TOC to non detectable limits. Analysis results and testing facility contacts are submitted along with this submission. [See Lab tests reports enclosed]

Test Labs Used

- AmeriWater Laboratories *(Test conformance to AAMI Standards)*
  1303 Stanley Ave,
  Dayton, OHIO 45404

- Culligan Water Testing Laboratory *(Test conformance to AAMI Standards)*
  9399 W.Higgins Road, Suite#1100
  Rosemont, IL 60018

- OXIDOR Laboratories, LLC *(Test for TOC)*
  1825 E. Plano Pkwy #160
  Plano, TX 75074

LAB ANALYSIS (Testing Lab: AmeriWater)

Component	Feed Water mg/L	Treated Water mg/L	AAMI Suggested Maximum Level mg/L	Meets or Exceeds AAMI Standard
Aluminum	0.001	<0.001	0.010	Yes
Antimony	<0.001	<0.001	0.006	Yes
Arsenic	<0.001	<0.001	0.005	Yes
Barium	0.013	<0.01	0.100	Yes
Beryllium	<0.0001	<0.0001	0.0004	Yes
Cadmium	<0.0001	<0.0001	0.0010	Yes
Calcium	30.09	<0.001	2.000	Yes
Chromium	<0.001	<0.001	0.014	Yes
Copper	0.107	<0.001	0.100	Yes
Fluoride	0.07	<0.01	0.200	Yes
Iron	0.027	<0.001	N/A	Yes
Lead	0.004	<0.001	0.005	Yes
Magnesium	13.22	<0.001	4.000	Yes
Mercury	<0.0001	<0.0001	0.0002	Yes
Nitrate (as N)	0.74	<0.01	2.000	Yes
pH	7.91	7.00	N/A	Yes
Potassium	3.736	<0.001	8.000	Yes
Resistivity	<0.001	0.699	N/A	Yes
Selenium	<0.001	<0.001	0.090	Yes
Silver	<0.001	<0.001	0.005	Yes
Sodium	26.64	0.289	70.000	Yes
Sulfate	79.60	<0.01	100.00	Yes
Thallium	<0.001	<0.001	0.002	Yes
TDS	180.50	0.64	N/A	Yes
Zinc	0.141	<0.001	0.100	Yes

9. Summary/Conclusion

The Ultrapure & Industrial Services, LLC. water purification components and the AmeriWater predicate device components are substantially equivalent to one another. All the water purification components and technology in this submission are comparable. Nonclinical tests conducted on the product water from a replicated exchange tank configuration verify product complies with AAMI-RD62 Standard. *We can confidently state that the performance testing demonstrates that the exchange tank devices perform to the same standard as that of the predicate.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2013

Ultrapure & Industrial Services, LLC
% Mr. Greg Franks
Quality Manager
4429 Mint Way
DALLAS TX 75236

Re: K123282
Trade/Device Name: Deionizer and Carbon Exchange Tanks for Hemodialysis
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: February 25, 2013
Received: March 22, 2013

Dear Mr. Franks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(K) Number: K123282

Device Name: Deionizer and Carbon Exchange Tanks for Hemodialysis

Indications for Use

The Ultrapure & Industrial Services **Deionization Tanks** are exchangeable/rechargeable mix bed tanks intended to remove ions from the water to a sufficient level to allow safe treatment of Hemodialysis patients. These deionization tanks are not to be used alone, but are intended to be a part of a larger water treatment system employing adequate pre-treatment and post treatment. Upon, exhaustion, these tanks will be replaced with other tanks containing newly regenerated resin, or new resin altogether.

Deionizer Models	
Model Number	**Cubic Feet**
UIS-618-MB-D	0.27
UIS-818-MB-D	0.48
UIS-844-MB-D	1.25
UIS-1047-MB-D	1.90
UIS-MB-1447-D	3.60

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123282

Indications For Use

510(K) Number: K123282

Device Name: Deionizer and Carbon Exchange Tanks for Hemodialysis

Indications for Use

The Ultrapure & Industrial Services **Carbon Exchange Tanks** are activated carbon tanks intended to remove chlorine and chloramines from the water to allow safe treatment of Hemodialysis patients. These carbon tanks are not to be used alone, but are intended to be part of a larger water treatment system employing adequate pre-treatment and post-treatment. Upon exhaustion, these tanks will be replaced with other tanks containing new activated carbon.

UIS Carbon Exchange Tank Models	
Model Number	**Cubic Feet**
UIS-618-GAC	0.27
UIS-818-GAC	0.48
UIS-844-GAC	1.25
UIS-1047-GAC	1.90
UIS-1447-GAC	3.60

All Ultrapure & Industrial Services Deionizer and Carbon Exchange Tank Service for hemodialysis are intended to be used in a hemodialysis facility according to ANSI/AAMI-RD62:2006 standards to supply purified water for use in hemodialysis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
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